UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) CONTAMINATION PRODUCTS LIABILITY LITIGATION	:	**HON. ROBERT B. KUGLER**
	:	**MASTER DOCKET NUMBER Civil No. 1:19-md-02875-RBK-JS**
This Document Relates to All Actions	:	

DECLARATION OF SCOTT MOONEY IN SUPPORT OF LETTER BRIEF OBJECTIONS AND MOTION FOR PROTECTIVE ORDER OF MCKESSON CORPORATION/WHOLESALERS ON "MACRO" DISCOVERY ISSUES ARISING FROM PLAINTIFFS' PROPOSED SET OF REQUESTS FOR PRODUCTION

I, Scott Mooney, hereby declare as follows:

Identification

1. My name is Scott Mooney. I have been employed by McKesson Corporation ("McKesson" or the "Company") since 1987. I have been corporate Vice President of Distribution Operations since 2013. The statements made in this declaration ("Declaration") are based upon my personal knowledge and information obtained during the course of my job duties and responsibilities. I have been employed by McKesson from 1987 to the present. Prior to acting as corporate Vice President of Distribution Operations, I was Regional Vice President of Distribution Operations.

Duties and responsibilities

2. As corporate Vice President of Distribution Operations, my job duties and responsibilities require that I be, and I am, familiar with McKesson's practices regarding: 1) the Drug Supply Chain Safety Act ("DSCSA") and its implementation at McKesson; 2) lead a qualified cross-functional team working to implement the standards and system necessary for DSCSA compliance across McKesson's pharmaceutical business unit, while supporting the

DSCSA implementation at McKesson's other business units such as Specialty Health, Medical Surgical and Packaging; and 3) work toward Distribution Operation compliance with FDA regulations, such as cold chain shipping and storage, and timelines.

3. My previous roles at McKesson include serving as a Regional Vice President of Distribution Operations with 7 distribution centers in the region, and acting as the Distribution Center Manager of the Lacrosse Distribution Center for 16 years. Finally, I was the Regional Controller for 5 years prior to my time as Distribution Center Manager at Lacrosse.

Plaintiffs' RFPs to Wholesalers and Specific Objections

4. I am familiar with Plaintiffs' proposed Set of Requests for Production of Documents to Wholesalers ("Draft RFPs" or "RFPs") (ECF 413-3). This Declaration supports the Wholesalers' letter brief ("Letter Brief") regarding Macro Discovery Issues, filed simultaneously herewith, generally, and supports McKesson's objections to and request for a protective order regarding such RFPs, specifically.

5. In particular, this Declaration supports McKesson's objections to RFPs 1 and 3 (the "Subject Requests"), in which Plaintiffs seek documents generated during the time period of January 1, 2012 until December 31, 2019 ("Requested Time Period") related to McKesson's purchases and sales of valsartan-containing drugs (VCDs) ("McKesson Purchase/Sale Info").

6. RFPs Nos. 1 and 3 specifically seek the following Wholesale Purchase/Sale Info to which McKesson objects and moves for protection:

- RFP No. 1 seeks the details of each individual purchase of VCDs from 2012-2019 from each Defendant Manufacturer, including each sale date, specific quantities purchased, lot/batch numbers sold, and expiration date.

- RFP No. 3 seeks the details of each individual sale date, specific quantities sold, lot/batch numbers sold, and expiration date.

Plaintiffs' Draft RFPs (ECF 413-3).

Federal Product Tracing History

7. There is a long history of Congress's regulation of tracing product in the pharmaceutical supply chain.

8. Neither Congress nor the FDA has ever required Wholesalers such as McKesson to trace their product sales by lot number through the supply chain.

9. By way of background, in 1987, the Prescription Drug Marketing Act of 1987 ("PDMA") was enacted (1) to ensure that drug products purchased by consumers are safe and effective, and (2) to avoid the unacceptable risk to American consumers from counterfeit, adulterated, misbranded, subpotent, or expired drugs.

10. The PDMA did not require *any* tier of the drug supply chain to pass along or trace lot numbers of pharmaceuticals sold.

11. Instead, the PDMA imposed a "Pedigree" requirement, which dictated that a statement identifying each sale of the drug (including the date of the sale), commonly called a "Pedigree," be passed along the supply chain.

12. However, the PDMA made special provision for "authorized distributors of record," meaning "those distributors with whom a manufacturer has established an on-going relationship to distribute such manufacturer's products." Other distributors who were not "authorized distributors of record" came to be known as "unauthorized" or "secondary" distributors. As a result, I hereafter refer to authorized distributors of record as "Primary Wholesale Distributors."

13. The PDMA specifically and expressly exempted Primary Wholesale Distributors from the Pedigree requirement.

14. Further, the Pedigree requirement was the extent of the PDMA's product tracing requirements. The PDMA did not require any party to provide lot information to another party in the supply chain. In other words, *no entity in the drug supply chain was required to perform lot-level tracing* under the original version of the PDMA.

15. In 1992, the PDMA was amended by the Prescription Drug Amendments of 1992 ("PDA"), but the requirements regarding tracing remained substantively the same: Secondary Wholesale Distributors, but not Primary Wholesale Distributors, were required to provide a Pedigree identifying each prior sale, purchase, or trade of such drug (including the date of the transaction and the names and addresses of all parties to the transaction).

16. When enacting the PDA, Congress explained that a Pedigree under the PDA "must in all cases include the dates of each transaction involving the drug and the names and addresses of all parties to the transaction, and must contain any such other information as the Secretary may require."

17. Notably, neither Congress nor the Secretary introduced any lot-level tracing requirements into the PDA's Pedigree requirement.

18. Thus, neither the original PDMA, nor the PDA, required lot-level tracing by any tier of the supply chain, and Primary Wholesale Distributors were exempted from even the transaction-based product-tracing Pedigree requirement.

19. In 1994, the FDA published final regulations (the "1994 Regulations") regarding the PDMA, as amended by the PDA.

20. The 1994 Regulations expanded the information required in a Pedigree to include: (1) the proprietary and established name of the drug; (2) dosage; (3) container size; (4) number of containers; (5) the drug's lot or control number(s); (6) the business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and (7) the date of each previous transaction (the "1994 Pedigree Requirements").

21. Thus, in 1994, the concept of lot-level tracing was introduced into the PDMA and PDA system for the first time.

22. The 1994 Pedigree Requirements now included lot information, but Primary Wholesale Distributors were still exempt from the Pedigree requirements, including the lot information requirement.

23. Yet, the 1994 Pedigree Requirements did not take effect in 1994. The FDA delayed the effective date of the 1994 Pedigree Requirements to December 1, 2006.

24. However, the 1994 Pedigree Requirements were short-lived, as they were only in effect for five days. On December 5, 2006, a federal district court judge enjoined the FDA from implementing the 1994 Pedigree Requirements, including the requirement that lot numbers be included in Pedigrees.

25. The injunction prevented the implementation of the 1994 Pedigree Requirements for years. Finally, in 2011, the FDA issued a proposed rule to remove the 1994 Pedigree Requirements, including the lot level information, altogether.

26. As such, the lot-level information portion of the 1994 Pedigree Requirements was never meaningfully implemented and was not enforced by the FDA.

27. But to reiterate, even if the 1994 Pedigree Requirements (such as the lot-level information requirement) had gone into effect (which they did not), Primary Wholesale Distributors like McKesson would have been exempt from those requirements.

Current Federal Drug Tracing Requirements

28. In 2013, Congress enacted the current pharmaceutical supply chain requirements via the Drug Supply Chain Security Act ("DSCSA").

29. The DSCSA sets forth the current product tracing requirements for each level of the pharmaceutical supply chain, and the requirements differ for each specific level of the supply chain.

30. Under the DSCSA, each tier of the supply chain, beginning with the Manufacturer, must pass along three things to purchasers: the transaction history, the transaction information, and a transaction statement. Collectively, these three things are called a "T3."

31. The DSCSA defines "transaction information" to mean:

> (A) the proprietary or established name or names of the product;
> (B) the strength and dosage form of the product;
> (C) the National Drug Code number of the product;
> (D) the container size;
> (E) the number of containers;
> (F) the lot number of the product;
> (G) the date of the transaction;
> (H) the date of the shipment, if more than 24 hours after the date of the transaction;
> (I) the business name and address of the person from whom ownership is being transferred; and
> (J) the business name and address of the person to whom ownership is being transferred.

32. Although the DSCSA was enacted in 2013, the DSCSA's T3 requirement did not take effect until 2015. *Therefore, the lot-level information in the T3 was not required to be passed along the supply chain until 2015.*

33. However, just as the old PDMA and PDA system did, the DSCSA made special provision for Wholesale Distributors who purchased a product directly from the manufacturer, the exclusive distributor of the manufacturer, or a repackager that purchased directly from the manufacturer. Therefore, I herein also refer to these Wholesale Distributors, as well as authorized distributors of record under the old PDMA and PDA system, as "Primary" Wholesale Distributors.

34. ***All of the Wholesaler Defendants in the present litigation – McKesson, Cardinal, and AmerisourceBergen – are Primary Wholesale Distributors who were specifically exempted from tracing lot information down the supply chain.***

35. Unlike Manufacturers, who are required to pass along lot information in their T3s to purchasers, Primary Wholesale Distributors are not required to include – and in fact, are explicitly exempted from including – the lot number in the T3s they provide to purchasers.

36. Instead, under the DSCSA, Primary Wholesale Distributors are simply required to *retain* the T3 received from the Manufacturer, which includes the lot numbers, for six years.

37. Thus, the Wholesaler Defendants are not required to, and do not: (1) input the lot number into their own data systems; or (2) pass it on to Retailers as part of a sale. As such, Wholesaler Defendants have no records or data that could connect a lot number to a sale to a Defendant Retailer.

38. In sum total, under the federal law spanning from the PDMA of 1987 to the current DSCSA, Primary Wholesale Distributors – such as the Wholesaler Defendants in this litigation – have *never* been required to trace lot-level information.

Pharmaceutical Supply Chain Processes

39. Primary Wholesale Distributors enter into Supplier Agreements with Manufacturers, under which Manufacturers agree to provide a variety of pharmaceuticals, listed by NDC numbers, to Wholesalers pursuant to various price calculations.

40. Supplier Agreements do not relate to one specific drug or class of drug (like valsartan-containing drugs or "VCDs"), but instead cover a variety of NDC numbers for a variety of drugs and classes of drugs.

41. An NDC number is a unique 10-digit or 11-digit, 3-segment number that acts as a universal product identifier for drugs in the United States. The first set of numbers in the NDC identifies the Manufacturer of the drug and the remainder of the number identifies the specific drug formulation and packaging of the drug.

42. Pursuant to the Supplier Agreements, Primary Wholesale Distributors make individual purchases of pharmaceuticals, including VCDs, from Manufacturers on an as-needed basis.

43. At the time that Primary Wholesale Distributors receive purchases of VCDs from Manufacturers, Manufacturers provide to Primary Wholesale Distributors lot number information through a T3 document under the DSCSA beginning on January 1, 2015.

44. Wholesalers also enter into Supplier Agreements with Retailers, under which Wholesalers agree to provide a variety of pharmaceuticals, listed by NDC numbers, to Retailers pursuant to various price calculations.

45. Pursuant to the Retailer Supplier Agreements, Retailers make individual purchases of pharmaceuticals on an as-needed basis.

46. When Primary Wholesale Distributors deliver the pharmaceuticals sold to the Retailers, Wholesalers provide a T3 to Retailers. However, pursuant to the DSCSA, a Primary Wholesale Distributor's T3 "shall not be required" to include lot-level information in this T3 and do not trace or link the lot numbers obtained from purchases from Manufacturers to product sold to Retailers.

47. The reason for the DSCSA's exemption – and correspondingly why Wholesaler Defendants do not have records or data that could connect a lot number to a sale to a Retailer – is technological limitation.

48. Supply chain participants do not yet have computer systems that are able to communicate with each other with the level of sophistication needed to connect a lot number to a sale to a Retailer.

49. In order to trace the tens of thousands of lot numbers of a VCD a Primary Wholesaler Distributor receives from Manufacturers and then link, out of those tens of thousands, a specific lot number to a specific sale to a particular Retailer, Wholesalers would be required to manually inspect each bottle of product and manually enter that information into their systems.

50. Wholesaler Defendants purchase product from Manufacturers in cases comprised of approximately 48 to 144 commercial-sized bulk bottles.

51. Wholesaler Defendants do not, however, generally sell cases of product; Wholesaler Defendants sell individual commercial-sized bulk bottles.

52. In order to trace which lot is being shipped as part of a specific sale, Wholesaler Defendants would need to look at the individual bottle and manually enter the lot number of each individual bottle into a system.

53. The work required to achieve lot number manual entry in order to trace each bottle would burden the supply chain, slowing down shipments and impacting delivery of pharmaceuticals to patients in need.

54. Primary Wholesaler Distributors like the Wholesaler Defendants work on slim margins, and the additional work involved in tracing lot number movement would likely erase profits, including in particular with respect to the sale of generic products.

55. Understanding that the costs to patients, the supply chain, and its participants of requiring Primary Wholesale Distributors to manually enter lot numbers in order to trace product through the supply chain outweighed the benefits, Congress enacted the specific exemption for Primary Wholesale Distributors, including the Wholesaler Defendants.

56. This Primary Wholesaler Distributor exemption will be in effect at least from 2015 to 2023. Pursuant to the DSCSA, by November 27, 2023, all levels of the supply chain must have an electronic, interoperable system in place to trace products by 2D barcode at the package level.

DSCSA Preemption

57. Congress recognized that a patchwork of State regulations governing pharmaceutical product tracing was unworkable.

58. Consequently, with the enactment of the DSCSA, Congress sought to create a uniform federal system for pharmaceutical product tracing.

59. Therefore, Congress in the DSCSA expressly forbade and preempted any product tracing requirements that are inconsistent with, more stringent than, or in addition to the product tracing requirements of the DSCSA.

60. As such, the DSCSA forbids attempts to require Primary Wholesale Manufacturers such as the Wholesaler Defendants to trace product by lot number through the supply chain.

Implications for the Current Litigation

61. In short, no amount of discovery from McKesson will allow Plaintiffs to trace lots from Wholesaler Defendants to Retailer Defendants and then into an individual Plaintiff's hands.

62. McKesson is expressly exempt from lot-level product tracing requirements under the DSCSA because it is a Primary Wholesale Distributor.

63. Because McKesson is exempt from lot-level product tracing requirements, McKesson does not conduct lot-level product tracing to the level of sales to Defendant Retailers, and does not possess any documents, system or other information that could trace which specific lot number(s) a Defendant Retailer received from McKesson through a sale of a VCD.

64. The only lot information that McKesson possesses is that information originally provided to them by Manufacturers. McKesson does not know – and there is no way to find out – the lots a specific Retailer Defendant received from McKesson.

65. McKesson, as a Primary Wholesale Distributor, simply does not create, provide, or retain records of where lots go via its distribution.

66. *The truth is that no amount of discovery from McKesson will allow Plaintiffs to trace lots from Wholesalers to a Retailer Defendant, let alone to an individual Plaintiff.*

67. Nothing in Wholesalers' Sales/Purchase Info could do more than that, or, more specifically, could establish which Wholesaler Defendant was involved in transporting a specific pill to a specific Consumer Plaintiff. ***That information is simply not possessed by Wholesaler Defendants and could not be re-created with the information available.***

68. As a result, production by McKesson of the documents requested in Plaintiffs' Draft RFPs 1 and 3 would not get Plaintiffs any closer to determining product traceability or lot information to the Defendant Retailer and/or Plaintiff level.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct, and that this declaration was executed June 4, 2020, in La Crosse, Wisconsin.

6-4-2020

Scott Mooney
Corporate Vice President of Distribution Operations
McKesson Corporation